DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The supplemental NADA provides for injection of ceftiofur hydrochloride suspension in cattle for the treatment of acute metritis.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7572, e-mail: cburnste@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplemental application to NADA 140–890 that provides for use of EXCENEL (ceftiofur hydrochloride) RTU Sterile Suspension by intramuscular or subcutaneous injection in cattle for the treatment of acute metritis (0 to 14 days post partum) associated with bacterial organisms susceptible to ceftiofur. The supplemental NADA is approved as of February 8, 2002, and the regulations are amended in § 522.314 (21 CFR 522.314) to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 522.314 is also being revised to reflect a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

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approval of this supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental application approval qualifies for 3 years of marketing exclusivity beginning February 8, 2002, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.314 is amended by revising the section heading, and paragraphs (a), (d)(1)(i), (d)(1)(iii), and (d)(2) to read as follows:

§ 522.314 Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of suspension contains ceftiofur hydrochloride equivalent to 50 milligrams (mg) of ceftiofur.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 3 to 5 mg per kilogram (/kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

* * * * *

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Dosage.* 1.1 to 2.2 mg/kg of body weight by intramuscular or subcutaneous injection, at 24-hour intervals for 3 to 5 consecutive days. For bovine respiratory disease, 2.2 mg/kg of body weight may be administered twice at a 48-hour interval. For acute metritis, administer 2.2 mg/kg of body weight daily for 5 consecutive days.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia* spp. (*Pasteurella haemolytica*), *P. multocida*, and *Haemophilus somnus*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post partum) associated with bacteria susceptible to ceftiofur.

(iii) *Limitations*. Do not slaughter treated cattle for 48 hours (2 days) after last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 6/26/02
June 26, 2002.

Andrew J. Beaulieu,
Acting Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
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